preparing a tetanus toxin composition comprising a fragment C and a fraction of fragment B of at least 11 amino acid residues in a composition for the treatment of the CNS or spinal cord disease; and

delivering the composition in a therapeutically effective manner.

Election

Applicants provisionally elect to prosecute Group II, claims 1-11 and 31, drawn to a method for *in vivo* delivery of a composition of protein to the CNS, with traverse.

Applicants also provisionally elect, with traverse, from Group A, a non-toxic proteolytic fragment of tetanus toxin comprising a fragment C and a fraction of fragment B of at least 11 amino acids.

And from Group B, Applicants provisionally elect protein SMN, with traverse.

Traverse

Groups I, II, and III

In the Action, the Office states that Groups I and II are distinct because Group I is drawn to gene therapy and Group II is drawn to protein therapy, and that the active ingredient in each method is distinct and cannot be used in the other method. (Office Action, page 2, lines 18-21.) The Office concludes that non-coextensive searches would be required. (Office Action, page 2, line 21.) The Office also states that distinctness is shown if the process for using the product as claimed can be practiced with another materially different product, or if the product as claimed can be used in a materially different process of using that product. (Office Action, page 2, lines 23-26.) Applicants respectfully submit that while those are factors in determining whether claims should be examined together, they are not the only factors.

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For example, it is respectfully submitted that the subject matter of all pending claims is sufficiently related that a thorough search of the subject matter of any one group of claims would encompass a search for the subject matter of the remaining claims. Thus, a search and examination of the non-elected subject matter with that of Group II would not place a serious additional burden on the Examiner. M.P.E.P. § 803 states that "if the search and examination of the entire application can be made without serious burden, the Examiner must examine it on the merits" (emphasis added herein by Applicants). It is respectfully submitted that this policy should apply in the present application in order to avoid unnecessary delay and expense to Applicants and duplicative examination by the Patent Office.

Additionally, for the same reasons, Applicants respectfully submit that, at the least, the Office should examine the polypeptide claims, restricted to Group III, with the claims of Group I. Examining the polypeptide claims of Group III with the method claims of Group I would not place a serious burden on the Examiner because these polypeptide claims encompass the polypeptides that are used in the method claims of Group I.

Groups A and B

The Office has also required restriction to one specific tetanus toxin polypeptide (Group A) and one specific molecule, such as those recited in claims 8 or 22 (Group B). In an effort to advance prosecution, Applicants have elected a specific toxin polypeptide from Group A and a specific molecule from Group B. However, Applicants respectfully traverse the propriety of the restriction.

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The Office states that the products defined by Groups A and B are distinct because each has a unique structural and functional feature, requiring a unique search of the prior art. Applicants respectfully submit that this is simply wrong. The "products" defined by Groups A and B may be described as non-toxic, proteolytic fragments of tetanus toxin and molecules with biological functions, respectively. They are species of the generic terms used in claim 1, but they do not define patentably distinct inventions.

At best, an election of species requirement may be made for these groups, thereby requiring Applicants to choose from a species disclosed. Because restriction in this instance is improper, but an election of species requirement may arguably be made, Applicants are treating this election as an election of species. Thus, Applicants reserve the right to request examination of additional species upon the indication of allowable species.

Conclusion

In conclusion, Applicants respectfully request that the Examiner withdraw the restriction/election requirements and consider all of the pending claims together and in their original form.

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PATENT
Customer No. 22,852
Attorney Docket No. 3495.0187-00

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: August 3, 2001

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APPENDIX TO AMENDMENT OF AUGUST 3, 2001

Amendments to the Claims

Please amend the claims as follows:

1. (AMENDED) A method for *in vivo* delivery of a desired composition into a human or animal central nervous system (CNS) or spinal cord, [wherein the method comprises] comprising administering to the human or animal a composition comprising a non-toxic, proteolytic fragment of tetanus toxin (TT) in association with at least a molecule having a biological function, wherein said molecule with a biological function comprises a protein, and wherein said composition is capable of *in vivo* retrograde axonal transport and transynaptic transport into the CNS or the spinal cord of the human or animal and of being delivered at different areas of the spinal cord.

6. (AMENDED) The method according to claim 1, wherein the [composition comprises a] non-toxic, proteolytic fragment of tetanus toxin (TT) [comprising] comprises a fragment C and a fraction of fragment B [or a fraction thereof] of at least 11 amino acid residues, [in association with at least a] and the molecule having a biological function [selected from the group consisting of] comprises a protein for compensation or modulation of functions under the control of the CNS or the spinal cord or modulation of functions in the CNS or the spinal cord [or a protein to be delivered by gene therapy expression system to the CNS or the spinal cord].

7. (AMENDED) The method according to claim 1, wherein the [composition comprises a] non-toxic, proteolytic fragment of tetanus toxin (TT) [comprising]

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comprises a fragment C and a fraction of fragment B [or a fraction thereof] of at least 11 amino acid residues [and a fraction of a fragment A devoid of its toxic activity corresponding to the proteolytic domain having a zinc-binding motif located in the central part of the chain between amino acids 225 and 245 in association with at least a], and the molecule having a biological function [selected from the group consisting of] comprises a protein for the compensation or the modulation of functions under the control of the CNS or the spinal cord [or protein to be delivered by gene therapy expression system to the CNS or the spinal cord].

31. (AMENDED) A method for the treatment of the central nervous system (CNS) or spinal cord disease comprising:

preparing a [Use of a hybrid fragment of] tetanus toxin [according to claim 18 or 19 of a polynucleotide fragment according to claim 20, or a composition according to anyone of claims 21 to 23, or a vector according to claim 24,] composition comprising a fragment C and a fraction of fragment B of at least 11 amino acid residues [for the preparation of] in a composition for the treatment of the CNS or [spiral] spinal cord disease; and

delivering the composition in a therapeutically effective manner.

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